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EXAMINER

KISHORE, GOLLAMUDI S 13

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/460,605

Applicant(s)

Disher

Examiner

Gollamudi Kishore

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 2, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 13-20, 23, and 25-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 13-20, 23, and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: :1615

DETAILED ACTION

The request for the extension of time and amendment dated 12-02-02 are acknowledged.

Claims included in the prosecution are 1-8, 10, 13-20, 23 and 25-29.

Claim Rejections - 35 U.S.C. § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 15-16, 23, and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

- 3. Claims 14-16, 21, 23 and 27-29 provide for the use of the polymersomes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.**

Claims 15-16, 21, 23, and 27-29 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in

Art Unit: :1615

an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Furthermore, claims 15 and 16 are confusing. According to claim 15, the material is removed from the surrounding environment; however, claim 16 recites the delivery of the material to the environment (patient). Similar is the case with claims 26-29. The examiner requested restructuring of the claims in the previous office action.

The distinction between a 'drug', 'a therapeutic composition' and a 'medicament' in claim 28 is unclear. Similar is the case with a 'nutrient', 'sugar', 'vitamin' and a 'mineral' (also in claim 14). In claim 14, it is unclear what 'waste product' is intended to convey. Applicant's arguments have been fully considered, but are not found to be persuasive since no evidence is provided. The only reference cited by applicant is Grant & Hackh's Dictionary for the definition of the term, 'drug'. As evidenced by the definition given in the dictionary itself, a drug is a 'medicinal substance' and instant claims recite 'medicament' besides 'drug'.

Applicant's arguments with regard to issue 3 in the 112, second paragraph rejection have been fully considered, but are not found to be persuasive. Applicant argues that the claim recites 'wherein the method comprises transporting at least one encapsulatable material to or from the environment immediately surrounding the polymersome and that 'transporting' is an active step satisfying the requirement that a method claim must have

Art Unit: :1615

and therefore s positive step. This argument is not found to be persuasive. The examiner is not questioning the delivery of the active agent to a patient using the claimed polymersome since the delivery of drugs using liposomes and polymerized liposomes is well known in the art. What is being questioned however, is how one can remove from a patient various agents recited in instant claims by administering a polymersome to a patient. For example, one of the agents recited in added claim 29 is a waste product. How can the waste product get inside the polymersome (assuming that the administered polymersome is empty) once the polymersome is inside the patient's body. Furthermore, while the removal of a waste product from the body is understandable, the rationale for removing a nutrient from the body is unclear. In essence, the claim language is so confusing. Furthermore, applicant has provided no guidance as to how this is done. With regard to claim 14:- this claim is included in the second paragraph rejection for the indefinite of the term, 'waste product'. On page 5 of the response, applicant states "Thus, polymersome may deliver an encapsulated material to a patient found in the patient so that it can be removed or excreted with the polymersome itself. If excretion is a method step, the examiner points out that excretion is a natural body function of humans (or any animal) and it is not an inventive method step.

Art Unit: :1615

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102

that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-4, 10, 13-15 and 25 are rejected under 35 U.S.C. 102(b) as being

anticipated by Ding (J. Phys. Chem., 1998) or Cornelissen (1998) or Fendler

(Science, 1984) all are of record.

The above references teach polymeric vesicles having a membrane; the polymers are diblock polymers (note abstracts in each). The references meet the requirements of instant claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Instant claims are product by process claims and therefore, considered as product claims. Deng teaches vesicles in water as evident from the paragraph bridging columns 1-2 on page 6109 and applicant has not shown that the vesicles of Deng are different from instant vesicles.

Applicant's arguments with regard to Fendler are not found to be persuasive. Applicant argues that Fendler teaches the formation of only structures from small lipid-

Art Unit: :1615

like amphiphiles with no more than four covalently cross-linkable bonds and that Fendler's formulations lack key characteristics of polymers, and only after vesicle-type formation does surfactant polymerization follow according to Fendler. These arguments are not found to be persuasive since the instant claims recite the molecular weight of the amphiphilic molecules as equal to or greater than 1400 and Fendler's polymerized vesicles using the surfactants listed on page 889 appear to meet at least this requirement of the lower molecular weight in instant claims. As pointed out before, the differences argued are not reflected in the claims.

Applicant amends the specification with regard to Cornelissen' teachings to substitute 'wholly synthetic' with 'semi- or partially synthetic' and argue that Cornelissen describes a polymer composed of natural amino acid L-alanine. This argument is not found to be persuasive since nowhere in Cornelissen the examiner can find that he used naturally occurring amino acid and not chemically synthesized amino acid. Therefore, the whole polymer in Cornelissen can be construed as a wholly synthetic (applicant's original description of Cornelissen's teachings).

Cornelissen reports the formation of bilayer filaments, a left-handed superhelix and collapsed vesicles and thus, in light of the co-existence of multiple structures, Cornelissen teaches not vesicles alone, but multiple structures in co-existence. This argument is not found to be persuasive since instant claim language does not exclude these structures; furthermore, a careful review of instant specification indicates the instant vesicles in

Art Unit: :1615

dominant co-existence with rod-like and spherical micelles (see the Fig. 1B description on page 9 of the specification).

Upon consideration, the 102 rejections over Hentze, and Liu are withdrawn.

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-6, 10, 13, 14 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornelissen cited above.

As pointed out above, Cornelissen teaches polymeric vesicles having a membrane; the amphiphilic block copolymers contain a poly(styrene) tail and a charged helical poly(isocyanide) head group derived from isocyano-L-alanine-L-alanine. Assuming that Cornelissen uses the naturally occurring L-alanine for the formation of the copolymers and not a synthetic one, in the absence of showing otherwise, it is deemed obvious to one of ordinary skill in the art that whether the amphiphilic copolymers are wholly synthetic or partially synthetic, they would still form vesicles since the vesicle

Art Unit: :1615

formation depends on the amphiphilic nature of the copolymer and not whether it is synthesized in the lab or naturally occurring.

8. Claims 3-8, 10 and 14-20, 23 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding or Fendler cited above.

The references of Ding, and Fendler are suggestive of the potential applications of the polymeric vesicles for the drug delivery. The use of the polymeric systems taught by Ding or Fendler for drug delivery would have been obvious to one of ordinary skill in the art since these references are suggestive of the drug delivery. As pointed out above, since some of the administered polymersomes are excreted by the host system, 'removal from the environment would have been obvious to one of ordinary skill in the art. The criticality of a triblock polymer is not readily apparent to the examiner since from the references it would appear that the amphiphilic nature of the polymer is the determinant factor.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on presumed lack of teachings of vesicles in the prior art. These arguments have been addressed above. As to applicant's arguments that none of the references teaches the use of the vesicles for drug delivery, the examiner points out that all of the references cited clearly teach the application of these polymers for drug delivery.

Art Unit: :1615

9. **Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).**

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: :1615

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

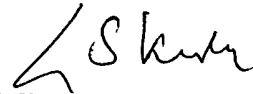
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Application/Control Number: 09/460,605

Page 11

Art Unit: :1615

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

March 21, 2003